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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/673,054	09/26/2003	Laurie Engel	02-1031-A	1228

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EXAMINER

FORD, VANESSA L

ART UNIT PAPER NUMBER

1645

DATE MAILED: 08/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/673,054

Applicant(s)

ENGEL ET AL.

Examiner

Vanessa L. Ford

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 June 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29, 67-77, 79 and 122-124 is/are pending in the application.
- 4a) Of the above claim(s) 4, 5 and 13-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 6-12, 16-28, 67-77, 79 and 122-124 is/are rejected.
- 7) ☒ Claim(s) 29 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

FINAL ACTION

1. This Office action is responsive to Applicant's amendment and response filed June 13, 2005. Claims 30-66, 78 and 80-121 have been cancelled. Claims 4-5 and 13-15 have been withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.
2. The text of those sections of the Title 35, U.S. code not included in this action can be found in the prior Office Action.

Objections/Rejections Withdrawn

3. In view of Applicant's amendments and remarks the following rejections are withdrawn:
 - a) Objection to the specification, page 4, paragraph 2.
 - b) Objection to the specification, page 5, paragraph 3
 - c) Objection to claims 67, 99-103, 108, 112, 114-117 and 121, page 5, paragraph 4.
 - d) Objection to claim 108, page 5, paragraph 5.
 - e) Objection to claim 78, page 5, paragraph 6.
 - f) Rejection of claims 9 and 101 under 35 U.S.C. 112, second paragraph, page 6, paragraph 7.
 - g) Rejection of claims 21 and 113 under 35 U.S.C. 112, second paragraph, page 6, paragraph 8.

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h) Rejection of claim 121 (only) under 35 U.S.C. 112, second paragraph, page 6, paragraph 9.

Objection/Rejection Maintained

4. The objection of claim 29 is maintained for the reasons set forth on page 6, paragraph 9 of the previous Office Action.

The objection was on the grounds that claim 29 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicant did not respond to this objection and therefore it is maintained.

5. The rejection under 35 U.S.C. 103(a) paragraph is maintained for claims 1-3, 6-12, 16-28, 67-77, 79 and 122-124 for the reasons set forth on pages 7-10, paragraph 10 of the previous Office Action.

The rejection was on the grounds that Chu et al teach compositions comprising aqueous solutions of alkylglycoside or alkythioglycoside, particularly (octylthiogluconate) (columns 1-2). Chu et al teach that the octylthiogluconate used in the compositions range from about 0.5 to about 5% w/v (column 2-3). Chu et al teach that the octylthiogluconate can be included in an aqueous solution at about 0.5% (v/w) to about 5% (v/w) (column 3). This meets the claims limitations "...at least 0.4% and less than 1% (w/v)" and "...between 0.4% and 0.6% (w/v)". Chu et al teach that buffers such as TRIS or HEPES can be added to the compositions to maintain a physiological pH of about 7-8 (column 2). Chu et al teach that the buffers can be maintained at a pH of 7.5 (column 3, Example II). Chu et al teach that lysozyme (reduces non-specific binding) can be added to the compositions (column 24, Example 4). Chu et al teach that the invention was used to prepare, extract, detect, purify and collect the isolated proteins (see Examples I-V, columns 3-6). Chu et al teach that the protein products are incubated on Nickel charged resins (magnetic) and further purified using spin columns

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comprising resins (Example V, columns 5-6). Chu et al teach compositions comprising aqueous solutions of octylthioglucoside used for lysing cells in the protein extraction process (columns 1-2) and Chu et al teach that the octylthioglucosides of the invention can release the protein of interest from the cell membrane or cell wall (column 2). Chu et al also teach that octylthioglucosides have been used for membrane solubilization (column 2). Therefore, claim limitations such as "wherein the cell altering compound inhibits phospholipid sensitive Ca^{+2} dependent protein kinase and attacks cell membranes" and "cell membrane compounds alters membrane permeability or disrupts membranes" are taught in the prior art reference.

Chu et al do not teach cationic surfactants comprising ethoxylated amine such as Tomah E -18-15 or Tomah E-18-5.

Shultz et al teach that cationic surfactants such as Tomah E -18-15 or Tomah E-18-5 are used to stabilize protein compositions (see the Abstract). Shultz et al teach that the cationic surfactants of the invention have a hydrophile-lipophile (HLB) index number of about 10 to 17, preferably about 11 to 16 (column 2). Shultz et al teach that cationic surfactants such as Tomah E -18-15 or Tomah E-18-5 can be used to stabilize proteins in both storage buffers and reaction enzymes (column 8). Shultz et al teach that the cationic surfactants can be added at concentrations ranging from 0.001% up to 1.0% (column 11). In re Venezia 189 USPQ 49 (CCPA 1976), where kits are drawn to the structural attributes of interrelated component parts and not to activities that may or may not occur. Thus, term "kit" constitutes an "intended use". Intended use does not impart patentable weight to a product. See MPEP 2111.03: Intended use recitations and other types of functional language cannot be entirely disregarded. However, in apparatus, article, and composition claims, intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. In re Casey, 370 F.2d 576, 152 USPQ 235 (CCPA 1967); In re Otto, 312 F.2d 937, 938, 136 USPQ 458, 459 (CCPA 1963).

It would be *prima facie* obvious at the time the invention was made to add Tomah E -18-15 and/or Tomah E-18-5 to aqueous solutions of Chu et al comprising octylthioglucosides because Shultz et al teach that cationic surfactants such as Tomah E -18-15 or Tomah E-18-5 can be used to stabilize proteins in both storage buffers and reaction enzymes in solution (see the Abstract and column 8). It would be expected barring evidence to the contrary that a composition comprising octylthioglucosides (cell-altering membrane), Tomah E -18-15 and/or Tomah E-18-5 (cationic surfactant), lysozyme (defoaming agent) and HEPES (buffer salt) would be effective in lysing cells to release proteins and stabilizing the proteins in reaction or storage buffers.

Applicant urges when claimed subject matter had been rejected as obvious in view of a combination of prior art references a proper analysis under 103 requires (1) whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition and (2) whether the prior art would also have revealed that in so making or carrying out, those of ordinary skill would have a reasonable expectation of success. Applicant urges that the prior art reference alone or in combination do not teach or suggest the claimed invention. Applicant urges that Chu et al is silent with respect to a composition having "at least one surfactant having a hydrophobic-lipophilic balance value in the range from about 11 to about 16" and further in combination with "at least one cell membrane altering compound". Applicant urges that Shultz et al adds nothing that remedies the deficiencies in the teachings of Chu et al. Applicant urges that Shultz et al do not suggest that detergents of any type in the HLB range of about 11-16 and is limited to cationic surfactants. Applicant urges that there is no incentive to select any surfactant in this HLB range in order to provide the composition as presently claimed. Applicant urges that Triton W-30 is listed as a surfactant that does not stabilize the enzyme activity and this anionic surfactant was demonstrated to operate the present invention. Applicant urges that selection of a material such as a surfactant to provide enzyme stability does not automatically presume that it will also provide effective lysis. Applicant urges that some surfactants can form micelles that act to provide additional stabilization of the cellular membrane proteins and makes extraction more difficult. Applicant that one of ordinary skill in the

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art would not be motivated to combine the teachings of Chu et al and Shultz et al to arrive at the claimed invention with any reasonable expectation of success.

Applicant's arguments filed June 13, 2005 have been fully considered but they are not persuasive. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the claims are directed to a composition comprising at least one surfactant having a lipophilic balance value in the range of about 11 to about 16 and at least one cell membrane altering compound. Chu et al teach compositions comprising aqueous solutions of octylthioglucoside used for lysing cells in the protein extraction process and further teach that the octylthioglucosides (cell membrane altering compound) of the invention can release the protein of interest from the cell membrane or cell wall. Chu et al do not teach cationic surfactants comprising ethoxylated amine such as Tomah E – 18-15 or Tomah E-18-5. However, Shultz et al teach that cationic surfactants such as Tomah E – 18-15 or Tomah E-18-5 are used to stabilize protein compositions. One of ordinary skill in the art would be motivated to add Tomah E – 18-15 and/or Tomah E-18-5 to aqueous solutions of Chu et al comprising octylthioglucosides because Shultz et al

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teach that cationic surfactants such as Tomah E –18-15 or Tomah E-18-5 can be used to stabilize proteins in both storage buffers and reaction enzymes in solution.

The Examiner disagrees with Applicant's assertions that "Chu et al is silent with respect to a composition having "at least one surfactant having a hydrophobic-lipophilic balance value in the range from about 11 to about 16" and further in combination with "at least one cell membrane altering compound". Shultz et al teach that cationic surfactants such as Tomah E –18-15 or Tomah E-18-5 are used to stabilize protein compositions and further teach that the cationic surfactants of the invention have a hydrophile-lipophile (HLB) index number of about 10 to 17, preferably about 11 to 16 (column 2). To address Applicant's comment regarding "Triton W-30, it should be noted that the prior art teaches several cationic compounds such as Tomah E –18-15 and/or Tomah E-18-5 that can be used to stabilize compositions. Therefore, Triton W-30 is not the only cationic surfactant taught by the prior art references. To address Applicant's comment regarding stability and effective lysis of surfactants, it should be noted that Shultz et al teach that Tomah E –18-15 or Tomah E-18-5 (surfactants) can be used to stabilize proteins and Chu et al teach that octylthioglucosides (cell membrane altering compound) used for lysing cells. Therefore, it should be remembered that it is the combination of all of the cited and relied upon references which make up the state of the art with respect to the claimed invention. Thus, one of ordinary skill in the art would expect success when combining the prior art reference to arrive at the claimed invention. There is nothing on the record to show that the combination of teachings would not suggest the claimed invention. Therefore, the rejection is maintained.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Status of Claims

7. No claims are allowed.


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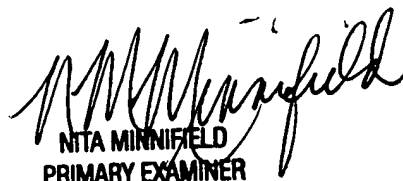
8. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 872-9306.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (571) 272-0857. The examiner can normally be reached on Monday – Friday from 9:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (571) 272-0864.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov/>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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August 16, 2005


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